DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 6,2014

Prismatik DentalCraft, Inc.
Armin Zehtabchi
Senior RA Specialist
2212 Dupont Drive, Suite P
Irvine California 92612

Re: K141887
Trade/Device Name: Obsidian ™ Press (All Ceramic and POM)
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Dated: August 26, 2014
Received: September 29, 2014

Dear Mr. Zehtabchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141887

Device Name
Obsidian™ Press (All-Ceramic and POM)

Indications for Use *(Describe)*
The Obsidian™ Press ceramic is used to fabricate Press Over Metal dental prostheses in the nature of crowns and bridges as well as monolithic dental prostheses in the nature of crowns, partial crowns, veneers, inlays, and onlays for posterior and anterior applications, as well as 3-unit anterior bridges (including pre-molar region as terminal abutment) using pressing methods.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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PRISMATIK DENTALCRAFT, INC.

006-510 (K) Summary-807.92(c)

This 510 (k) summary is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

A. SUBMITTER INFORMATION

Company Name:	Prismatik Dentalcraft, Inc.
Company Address:	2212 Dupont Dr., Suite P, Irvine, CA 92612
Company Phone:	949-225-1269
Company FAX:	949-553-0924
Facility Registration Number:	3005477956
Primary Contact Person:	Armin Zehtabchi, (949) 225-1234 Senior RA Specialist
Secondary Contact Person	Marilyn Pourazar, (949) 225-1269 Senior Director, RA/QA
Date Summary Prepared:	November 5, 2014

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Obsidian™ Press (All-Ceramic and POM)
21 CFR Reference:	21 CFR 872.6660
21 CFR Common Name:	Porcelain powder for clinical use
Classification:	Class II, EIH
Panel:	Dental

PRISMATIK DENTALCRAFT, INC.

C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name:

- Obsidian™ Ceramic Blocks-K100781
- IPS e.max Press and IPS e.max Press Multi (Ivoclar Vivadent, Incorporated)-K120134
- IPS 99 One and IPS 99 Ceram (Ivoclar Vivadent, Incorporated)-510(k)-K121359

D. DEVICE DESCRIPTION

Obsidian™ Press is a lithium silicate ceramic to be supplied in the form of ingots to be pressed to temperature in various furnaces. The increased Obsidian™ Press CTE value is intended to allow the Obsidian™ Press ceramic to be used in Press Over Metal applications, using various approved dental alloys, in addition to the all ceramic applications. The ingots are designed to be pressed into a variety of restorations including Press Over Metal (POM) such as full contour crowns and bridges, as well as monolithic all-ceramic restorations such as full contour crowns, up to 3-unit anterior bridges (including pre-molar region as terminal abutment), inlays, onlays, partial crowns, and veneers with esthetics, translucency, and strength. The ingots will be available in the commonly used VITA Classical and Chromascop Bleach shades.

E. INDICATIONS FOR USE

The Obsidian™ Press ceramic is used to fabricate Press Over Metal dental prostheses in the nature of crowns and bridges as well as monolithic dental prostheses in the nature of crowns, partial crowns, veneers, inlays, and onlays for posterior and anterior applications, as well as 3-unit anterior bridges (including pre-molar region as terminal abutment) using pressing methods.

F. DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The comparison table below outlines and provides the similarities and the substantial equivalency of the predicate devices, Obsidian™ Ceramic Blocks, 510(k)-K100781, IPS e.max Press and IPS e.max Press Multi (Ivoclar Vivadent, Incorporated), 510(k)-K120134, IPS 99 One and IPS 99 Ceram (Ivoclar Vivadent, Incorporated), 510(k)-K121359 and the proposed device, Obsidian™ Press (All-Ceramic and POM), and Prismatik believes that the comparative data presented in the preceding paragraphs, demonstrate that Obsidian™ Press (All-Ceramic and POM) is essentially the same as currently marketed devices for the same indication for use, and supports our claim of substantial equivalence to predicate Class II devices under the classification of Porcelain powder for clinical use (21 CFR 872.6660) that have previously been found to be substantially equivalent, and that any differences between the proposed device, Obsidian™ Press (All-Ceramic and POM) and the predicate device do not introduce any new issues of safety or effectiveness.

PRISMATIK DENTALCRAFT, INC.

Table 1 – Comparison between Predicate and Proposed Device

Attributes	Predicate Devices			Proposed Device	Similarities and Differences Between the Predicate and the Proposed Device
		IPS e.max Press and IPS e.max Press Multi (Ivoclar Vivadent, Incorporated) 510(k)K120134	IPS 99 One and IPS 99 Ceram (Vivadent, Incorporated) 510(k)-K121359		
Indications for Use	This device is used to fabricate ceramic dental prostheses in the nature of crowns and bridges for posterior and anterior applications using CAD/CAM or hot-press methods.	IPS e.max Press and IPS e.max Press Multi is an all-ceramic system for the creation of Occlusal veneers Thin Veneers Veneers Inlays Onlays Crowns in the anterior and posterior region 3-unit bridges in the anterior region 3-unit bridges in the premolar region up to the second premolar as the terminal abutment Crown, splinted crown or 3 unit bridge up to the second premolar placed on top of an implant abutment.vice0	IPS 99 One is a one-layer veneering ceramic for the fabrication of metal-ceramic restorations using the most popular dental alloys in the CTE range of 13.8-15.0 x 10-6/K (25-500°C) IPS 99 Ceram is a conventional multi-layer veneering ceramic for the fabrication of metal ceramic restorations using the most popular dental alloys in the range of 13.8-15.0 x 10-6/K (25-500°C). IPS 99 is intended to be used for inlays, onlays, veneers, and anterior/posterior PFM crowns.	The Obsidian™ Press ceramic is used to fabricate Press Over Metal dental prostheses in the nature of crowns and bridges as well as monolithic dental prostheses in the nature of crowns, partial crowns, veneers, inlays, and onlays for posterior and anterior applications, as well as 3-unit anterior bridges (including pre-molar region as terminal abutment) using pressing methods.	Substantially equivalent
Shades	A1, A2, A3, A35, B1, B2, B3, C1, C2, C3, D2, D3, BL1 and BL4	High and low translucencies): 16 A-D and 4 Bleach BL shades	A1, A2, A3, A35, B1, B2, B3, C1, C2, D2, D3, BL1 and BL4	A1, A2, A3, A35, B1, B2, B3, C1, C2, D2, D3, BL1 and BL4	Same
Flexural Strength	>300 MPa (meeting ISO 6872 requirements)	>300 MPa (meeting ISO 6872 requirements)	>300 MPa (meeting ISO 6872 requirements)	>300 MPa (meeting ISO 6872 requirements)	Same
Chemical Solubility	< 100µg/cm² (meeting ISO 6872 requirements)	< 100µg/cm² (meeting ISO 6872 requirements)	< 100µg/cm² (meeting ISO 6872 requirements)	< 100µg/cm² (meeting ISO 6872 requirements)	Same

Attributes	Predicate Devices			Proposed Device	Similarities and Differences Between the Predicate and the Proposed Device
	Obsidian™ Ceramic Blocks 510(k)-K100781	IPS e.max Press and IPS e.max Press Multi (Ivoclar Vivadent, Incorporated) 510(k)-K120134	IPS 99 One and IPS 99 Ceram (Vivadent, Incorporated) 510(k)-K121359	Obsidian™ Press (All Ceramic and POM)	
Freedom from Extraneous Material	Shall be free from extraneous materials when assessed by visual inspection (meeting ISO 6872 requirements)	Shall be free from extraneous materials when assessed by visual inspection (meeting ISO 6872 requirements)	Shall be free from extraneous materials when assessed by visual inspection (meeting ISO 6872 requirements)	Shall be free from extraneous materials when assessed by visual inspection (meeting ISO 6872 requirements)	Same
Radioactivity	Activity concentration of uranium^{238} less than 1.0Bq g^{-1} (meeting ISO 6872 requirements)	Activity concentration of uranium^{238} less than 1.0Bq g^{-1} (meeting ISO 6872 requirements)	Activity concentration of uranium^{238} less than 1.0Bq g^{-1} (meeting ISO 6872 requirements)	Activity concentration of uranium^{238} less than 1.0Bq g^{-1} (meeting ISO 6872 requirements)	Same
Coefficient of Thermal Expansion (25-500°C)	12.2+/-0.5 x10^{-6} °C (meeting ISO 6872 requirements)	12.2+/-0.5 x10^{-6} °C (meeting ISO 6872 requirements)	12.2+/-0.5 x10^{-6} °C (meeting ISO 6872 requirements)	12.2+/-0.5 x 10^{-6} °C (meeting ISO 6872 requirements)	Same
Biocompatibility	Non-toxic and biocompatible (Meeting the ISO 10993-5 and 10993-10 Requirements)	Non-toxic and biocompatible (Meeting the ISO 10993-5 and 10993-10 Requirements)	Non-toxic and biocompatible (Meeting the ISO 10993-5 and 10993-10 Requirements)	Non-toxic and biocompatible (Meeting the ISO 10993-5 and 10993-10 Requirements)	Same

G. SUMMARY OF NON-CLINICAL TESTING/PERFORMANCE DATA

To meet the ISO 6872 requirements, various non-clinical and applicable tests were performed, and the tests results for the Flexural Strength, Chemical Solubility, Freedom from Extraneous Material, Radioactivity, and Coefficient Thermal Expansion indicate the Obsidian™ Press (All Ceramic and POM) is comparable to the predicate devices.

In addition, the Obsidian™ Press (All-Ceramic and POM) has been tested for Cytotoxicity (ISO 10993-5), Sensitization (ISO 10993-10), and Irritation (ISO 10993-10) to meet the biocompatibility requirement and the reports are as follow:

- The Cytotoxicity Report shows that there was no reaction on any of the cells.
- The Sensitization Report shows that there was no reaction on the tested subject.
- The Irritation Report shows that there was no erythema or edema on the test subject.

Test Description	Results
Cytotoxicity Study using the IX MEM extraction method at 37°C	Pass
ISO Intracutaneous Study, Extract 0.9% sodium chloride USP solution (SC) and sesame oil, NF (SO)	Pass
Irritation and Skin Sensitization Study, Extract 0.9% sodium chloride USP and sesame oil, NF (SO)	Pass

A copy of the tests result is provided in the **Attachment A**.

H. CONCLUSION FROM THE NON-CLINICAL TESTING/ PERFORMANCE DATA

The proposed Obsidian™ Press (All-Ceramic and POM) has the same performance specifications, fundamental scientific technology and intended use as that of the predicate devices, Obsidian™ Ceramic Blocks 510(k)-K100781, IPS e.max Press and IPS e.max Press Multi (Ivoclar Vivadent, Incorporated), 510(k)-K120134 and IPS 99 One and IPS 99 Ceram (Ivoclar Vivadent, Incorporated), 510(k)-K121359. These devices are substantially equivalent, and that any differences between the Obsidian™ Press (All-Ceramic and POM) and the cited predicate devices do not introduce any new issues of safety or effectiveness.